Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 17–108 are herein cancelled without prejudice. Claims 109–179 have been added; support for these claims may be found, e.g., in original claims 30–108 and Examples 3 and 4. Each of claims 109–179 is a combination that requires presence of a product of claim 1 or claim 16 (e.g., claims 109–121 and 138–144) or a method of using a product of claim 1 or claim 16 (e.g., claims 122–137 and 145–179). Because claims 109–121 and 138–144 are related to claims 1 or 16 as combination-subcombination, it is improper to restrict these new claims from claims 1–16. *See* M.P.E.P. § 806.05(c) (2004). Because claims 145–179 require use of the products of claim 1 or 16, these claims—if withdrawn—should be rejoined upon allowance of claims 1 and 16.

The rejection of claims 1–16 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,673,901 to Koide (the "'901 Patent") is respectfully traversed.

The analysis of an obviousness-type double patenting rejection parallels the analysis of an obviousness determination under 35 U.S.C. § 103 (*In re Berg*, 140 F.3d 1428, 1431–1432; 46 USPQ2d 1226, 1229 (Fed. Cir. 1998)), however the analysis is limited to comparing the scope of the claims between the application and the cited patent (*see* M.P.E.P. § 804 (2004)).

Claim 1 of the '901 Patent relates to a fibronectin type III polypeptide monobody that binds to a specific binding partner (SBP) to form a polypeptide:SBP complex. None of claims 2–16 of the '901 Patent further define the SBP as a nuclear receptor. Claims 1–16 of the present invention relate to a fibronectin type III (Fn3) polypeptide monobody that *exhibits nuclear receptor binding activity*.

The PTO has not established a prima facie case of obviousness. Whether the claimed species (monobodies that exhibit nuclear receptor binding affinity) is encompassed by the prior art genus (monobodies that bind to a specific binding partner) is not sufficient by itself to establish a prima facie case of obviousness. M.P.E.P. § 2144.08(II) (2004) (citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994); *In re Jones*, 958 F.2d 347, 350, 21 USPQ2d 1941, 1943 (Fed. Cir. 1992)). To establish a prima facie case of obviousness over the claims of the '901 Patent, the PTO must demonstrate that the claims of

the '901 Patent teach or suggest all the claim limitations. Claim 1 of the '901 Patent, however, fails to explicitly claim (let alone identify) monobodies that exhibit nuclear receptor binding affinity, nor does claim 1 of the '901 Patent suggest modifying the monobody to render it capable of binding to a nuclear receptor. (Indeed, the PTO does not even assert that nuclear receptor binding affinity is disclosed or suggested in any claims of the '901 Patent.) Because the claims of the '901 Patent do not teach or suggest all the limitations of claim 1 of the present invention, neither claim 1 nor claims 2–16 dependent thereon would have been obvious over the claims of the '901 Patent. Therefore, the rejection of claims 1–16 for obviousness-type double patenting over the '901 Patent is improper and should be withdrawn.

The rejection of claims 1–16 under 35 U.S.C. § 102(b) as being anticipated by WO 98/56915 to Koide (the "PCT Application") is respectfully traversed.

The PCT Application relates to fibronectin type III polypeptide monobodies. However, like claim 1 of the '901 Patent, the PCT Application does not expressly disclose monobodies that exhibit nuclear receptor binding affinity, as required by the present claims. Indeed, the PTO has failed to even assert that the PCT Application teaches any polypeptide monobodies that have nuclear receptor binding affinity, let alone identify where in the PCT Application such monobodies are disclosed.

Additionally, there is no objective basis to conclude that the monobodies disclosed in the PCT Application inherently have nuclear receptor binding affinity. Firstly, the specific monobodies disclosed in the PCT Application were not shown to bind to any nuclear receptors. Secondly, the BC and FG loop region sequences disclosed in the PCT Application do not match the BC and FG loop region sequences of the monobodies disclosed in the present application that bind to a nuclear receptor (e.g. estrogen receptor). Therefore, there is no objective basis for the PTO to infer that the PCT Application monobodies would inherently bind to nuclear receptors, and the PTO has failed to suggest otherwise (let alone identify a basis for such suggestion). Because the PCT Application fails to teach each and every element of claim 1 of the present invention, it cannot anticipate claim 1 (nor claims 2–16, which depend therefrom). Therefore, the rejection of claims 1–16 for anticipation by the PCT Application is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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